Field Safety Notice

November 23, 2021 | MX- 8398 | Rev 1

MCC/21/005/IU: Sevoflurane vaporizers for Flow Family Anesthesia systems

Products affected:

Item number	Getinge Order Reference	Serial number
6886601	Vaporizer Sevoflurane Maquet filling	See consignee list
6887523	Vaporizer Sevoflurane SAFE-T-SEAL	See consignee list

The vaporizer is a component in the Flow family anesthesia systems, used for containing and vaporizing the anesthetic agent. Sevoflurane is a sweet-smelling, nonflammable, highly fluorinated methyl isopropyl ether used as an inhalational anesthetic for induction and maintenance of general anesthesia.

The Sevoflurane vaporizers are approved by Getinge for the following brands: AbbVie Sevorane®/Ultane®, Sevoflurane Piramal and Baxter Sevoflurane.

- Item No. 6886601, Vaporizer Sevoflurane, Maquet filling is used with AbbVie Sevorane®/Ultane®, Sevoflurane Piramal and Baxter Sevoflurane.
- Item No. 6887523, Vaporizer Sevoflurane, SAFE-T-SEAL is used with Baxter Sevoflurane.

The item number may be found in the label located underneath each vaporizer, see image below.

Description of the issue

Sevoflurane is susceptible to various types of chemical degradation. Notably, the most relevant is the degradation Lewis acids. These are acid substances that accept a pair of nonbonding electrons, also known as an electron-pair acceptor (e.g. metal oxides and metal halides). Sevoflurane is also susceptible to hydrofluoric acid, and to other toxic compounds.

Maquet Critical Care has received eight complaints describing the presence of a yellow substance in the vaporizer. Hydrogen fluoride has been confirmed in one complaint by chemical analysis. While in one instance

the complaint stated that a smell was detected, it was reported that for four complaints the vaporizers didn't pass system checkout and that one unit had noted leakage.

No patient or operator adverse events have been reported in any of these complaints.

This issue has only been observed when using Sevoflurane Piramal and Baxter Sevoflurane. No complaints have been reported for Abbvie Sevorane®/Ultane®. Due to the formulation of AbbVie Sevorane®/Ultane® it can be continued to be used.

Potential hazards

The potential hazards that have been identified include inhalation of hydrogen fluoride. Potential harms may include irritation of respiratory tract and in worst case may lead to lung edema and/or severe hypocalcemia which may be delayed for 24-48 hours after exposure.

No patient or operator adverse events have been reported in any of these complaints.

Precautions

Until further notice do not use the following:

- 6886601, Vaporizer Sevoflurane, Maquet filling with Sevoflurane Piramal and Baxter Sevoflurane
- 6887523, Vaporizer Sevoflurane, SAFE-T-SEAL with Baxter Sevoflurane

Until further notice, do not use:

- Vaporizer model 6886601 if previously used with Sevoflurane Piramal and/or Baxter Sevoflurane, even if currently used with AbbVie Sevorane®/Ultane®.

Note that the vaporizers still can be used in the following cases:

- Vaporizer model 6886601 may remain in use if it has only been used with AbbVie Sevorane®/Ultane®.

- Vaporizer Isoflurane models 6682280 & 6886621, Maquet filling, are not affected by this issue and its use may continue.
- Vaporizer Desflurane models 6682287 & 6886631, Safe-Fil, are not affected by this issue and its use may continue
- Vaporizer Sevoflurane models 6682285 & 6886611, Quik-Fil, are not affected by this issue and its use may continue
- Vaporizer Sevoflurane model 6682282, Maquet fill, are not affected by this issue and its use may continue
- Vaporizer Sevoflurane model 6887135, SAFE-T-SEAL, are not affected by this issue and its use may continue

Handling

Hydrogen fluoride is a toxic and hazardous acid and must be handled with care depending on its concentration for the safety of patients and operators. The observed concentrations are below the concentrations considered hazardous for handling by current literature.

If no sign of discoloration/corrosion or smell handle them according to the instructions for use for the Flow family anesthesia systems when removing them for storage.

As a precaution if signs of discoloration/corrosion or smell use general safety aspects handling chemicals such as protective gloves and protective goggles when removing them for storage without emptying them. Contact your Getinge representative for further actions.

In case of skin contact rinse with water immediately. If clothing has been contaminated, remove immediately and dispose them.

Corrective action

While the investigation is ongoing a root cause has not been determined. Getinge will continue to investigate and will provide an updated Field Safety Notice once the root cause and/or corrective actions are identified. We urge to maintain awareness on this notice and related actions until further communication from Getinge. Please complete & return the attached acknowledgement form.

Distribution

The respective competent health authorities have been informed about this communication and issue.

This Getinge Field Safety Notice distribution must include those individuals that need notification within your organization - or any organization where the potentially affected devices have been transferred. Please keep notice of this and subsequent communications to ensure that the appropriate corrective actions are taken while using the device. It is understood that failure to respond to this Field Safety Notice or to proceed with the corrective action requests described above may dispense Getinge from any liability connected with or arising out of this Field Safety Notice. The submission of this notice shall not be construed as an admission of liability for the issue described herein and its consequences.

We apologize for any inconvenience that this may have caused and will do our utmost effort to provide a reasonable solution as swiftly as possible.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Lena Evander
Director Product Mgmt. Anesthesia
Maquet Critical Care AB

Jerker Åberg
Manager Regulatory Affairs & Product Compliance
Maquet Critical Care AB

CONFIRMATION OF RECEIPT

Return this form to:

Getinge Representative: _____

Email: _____

Field Safety Notice MX-8398/Field Corrective Notice MX-8397
2021-11-25
Flow Family Anesthesia systems
Field Action – Immediate Update – Sevoflurane Vaporizers

We herewith confirm that we have received this Field Safety Notice.

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Hospital name

…….. ……..
Country Name of recipient

…….. ……..
Date Signature

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